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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/706,424		11/12/2003	Richard H. Ffrench-Constant	62,878A	5813				
25212	7590	01/12/2006		EXAM	INER				
DOW AGE	ROSCIE	NCES LLC		KUBELIK	ANNE R				
9330 ZIONS INDIANAP		_	ART UNIT	PAPER NUMBER					
INDIANAE	OLIS, II	4 40200	1638						
·			DATE MAILED: 01/12/2006						

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Applicant(s)											
10/706,424 FFRENCH-CONSTANT ET AL.											
Office Action Summary Examiner Art Unit											
Anne R. Kubelik 1638											
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply											
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).											
Status											
1) Responsive to com	1) Responsive to communication(s) filed on 17 October 2005.										
2a) This action is FINAL	_										
3) Since this application	Since this application is in condition for allowance except for formal matters, prosecution as to the ments is										
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.											
Disposition of Claims											
4) Claim(s) 1-14 is/are pending in the application.											
4a) Of the above cla	im(s) is/are withdra	wn from consideration.									
5) ☐ Claim(s) <u>1 and 2</u> is/s	are allowed.										
6) ☐ Claim(s) 3-14 is/are	rejected.	•									
7) Claim(s) is/a	re objected to.										
8) Claim(s) are	subject to restriction and/o	r election requirement.									
Application Papers											
9)⊠ The specification is o	bjected to by the Examine	er.									
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.											
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).											
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).											
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.											
Priority under 35 U.S.C. § 119											
12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) ☐ All b) ☐ Some * c) ☐ None of:											
1. Certified copies of the priority documents have been received.											
2. Certified copies of the priority documents have been received in Application No											
3. Copies of the certified copies of the priority documents have been received in this National Stage											
application from the International Bureau (PCT Rule 17.2(a)).											
* See the attached deta	ailed Office action for a list	of the certified copies not receive	ed.								
Attachment(s)											
1) Notice of References Cited (P1		4) Interview Summary									
Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date											

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DETAILED ACTION

1. Applicant's election of Group IV and nucleic acids encoding SEQ ID NO:10 in the reply filed on 17 October 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

- 2. The title of the invention is not descriptive of the instantly claimed invention. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.
- 3. The abstract is not descriptive of the instantly claimed invention. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

Claim Objections

4. Claims 3-10 and 12 are objected to because of the following informalities:

Claims 3-5, line 2, have an improper article before "protein".

Claim 5 repeats "nucleic acid" in line 1.

Claims 6-9 start with an improper article and are missing a comma after "5".

Claims 10-11 should start with an article.

In claim 10, an article missing before "seed".

In claim 12, line 3, --the group consisting of-- should be inserted after "selected" and "or" should be replaced with --and--.

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Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A full review of the specification indicates that nucleic acids encoding TcdA1, TcdB1 and TccC2 are essential to the operation of the claimed invention. The claimed methods encompass the use of a nucleic acid encoding any TcdA1, TcdB1 and TccC2; however, the specification describes no such nucleic acids. While the prior art describes some examples of nucleic acids encoding TcdA1, TcdB1 and TccC2, the structural features that distinguish TcdA1 from other TcdA-like proteins is unclear; TcdA1 from *Photorhabdus luminescens* W14 is more similar to TcdA2 than it is to TcdA1 from *X. nematophilus* (Waterfield et al 2001, Trends Microbiol. 9:185-191; Fig 3). Similarly, the structural features that distinguish TccC2 from other TccC-like proteins is unclear; TccC2 from *P. luminescens* W14 is more similar to TccC1 from *P. luminescens* W14 than it is to TccC2 from other bacteria. Thus, the structural features that distinguish TcdA1, TcdB1 and TccC2 from other TcdA-like, TcdB-like and TccC-like proteins are not described in the prior art or the specification.

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Hence, Applicant has not, in fact, described nucleic acids that encode TcdA1, TcdB1 and TccC2 within the full scope of the claims. Because the sequences are not described, the method of using the sequences to produce toxin is likewise not described, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the compositions used in the claimed methods, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

7. Claims 3-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to plants, plant cells and seeds transformed with only a nucleic acid encoding SEQ ID NO:10, which encodes TcdB2 from *Photorhabdus luminescens* W14.

The instant specification, however, only provides general guidance for expression of proteins in plants; no working examples in which insect resistant plants, plant cells or seeds transformed with only a nucleic acid encoding SEQ ID NO:10 are presented.

The instant specification fails to provide guidance for how to use plants, plant cells and seeds transformed with only a nucleic acid encoding SEQ ID NO:10.

Waterfield et al (2001, Appl. Environ. Microbiol. 67:5017-5024) teach that in S. entomophila, which has toxin homologs to tcdA, tcdB and tccC, expression of all three is

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required to produce active toxin (paragraph spanning pg 5023-5024). This suggests that plants expressing tcdB1 (SEQ ID NO:10) alone would not be insect resistant. As Applicant provided no working examples that show that plants expressing SEQ ID NO:10 alone are insect resistant, the unpredictability suggested by the art is not overcome.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

In it unclear in claims 12-14 what the practitioner of the method must do to express the DNAs in a host, given that the DNAs do not have inducible promoters operably linked to them.

10. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are promoters operably linked to each DNA to permit their expression in the host cells.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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12. Claims 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kramer et al (2001, US Patent 6,281,413).

Kramer et al teach a nucleic acid that encodes "a" protein of SEQ ID NO:10, and plants, plant cells and seeds comprising it; the plants include rice, maize, tobacco and cotton (column 8, lines 17-45; column 15, lines 33-58; column 46,, line 4, to column 48, line 25, claims 1-20). The rejection is made because a nucleic acid that encodes "a" protein of SEQ ID NO:10 includes nucleic acids that encode the full-length sequence of SEQ ID NO:10 and those that encode any portion of SEQ ID NO:10.

- Claims 1-2 and 12-14 are free of the prior art, given the failure of the prior art to teach or suggest isolated nucleic acids encoding SEQ ID NO:10. The closest prior art is Waterfield et al (2001, Trends Microbiol. 9:185-191) and Kramer et al (2001, US Patent 6,281,413) who teach nucleic acids that encode proteins with 75/9% and 76.1% identity, respectively, to SEQ ID NO:10 (see search results).
- 14. Claims 1-2 are allowed.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Anne Kubelik, Ph.D. January 6, 2006

ANNE KUBELIK, PALA BRIMARY EXAMINER

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17	139.5	1.8	646	N	US-09-902-540-10353	0
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                                                                                                                                KGKDVVQSGDITLPVPGADPRKLVAPSDVLGSGQAHLVEVSATKVTCWPNLGRGRFGQPI
                           EQDG-NVVILPPLELAYQDFSPRHHAHWQPMDVLANFNAIQRWQLVDLKGEGLPGLLYQD
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GENERAL INFORMATION:
APPLICANT: Efranch-Constant, Richard
APPLICANT: Bowen, David
APPLICANT: Rocheleau, Thomas
APPLICANT: Waterfield, Nicholas
TITLE OF INVENTION: DNA SEQUENCES FROM PHOTORHABDUS LUMINESCENS
FILE REFERENCE: 61645
CURRENT APPLICATION NUMBER: US/09/817,514A
CURRENT FILING DATE: 2000-03-26
PRIOR APPLICATION NUMBER: US 60/191806
PRIOR PLING DATE: 2000-03-24
NUMBER OF SEQ ID NOS: 8
SOFTWARE: Patentin version 3.0
SEQ ID NO 4
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Best Local Similarity 75.9%; Pred. No. 0;
Matches 1120; Conservative 122; Mismatches 224; Indels
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                                                                                                                                                                     Sequence 4, Application US/09817514A Patent No. 6639129
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TNSIGLPPHNLTLTPDRYDRDSGQQIHQQVAFSDGFGRLLQASVRHEAGEAWQRNQDGSL 1380
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                                         FREALM.#14;

MEDLINE=22454990; PubMed=12564983; DOI=10.1016/S0966-842X(02)02463-0; MEDLINE=22454990; PubMed=12564983; DOI=10.1016/S0966-842X(02)02463-0; MALEIRELAID NR., Daborn P.J., freench-Constant R.H.;

Trends Microbiol. 10:541-545(2002).

EMBL; AF345600; AAL18497.1; -; Genomic_DNA.

GO; GO:0005737; C:cytoplasm; IEA.

GO; GO:0007160; P:cell-matrix adhesion; IEA.

InterPro; IPR00413; Integrin alpha.

InterPro; IPR003284; Sal_SpvB.

Pfam; PF03534; SpvB; 1.
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MEDLINE=21185117; PubMed=11286884; DOI=10.1016/S0966-842X(01)01978-3; Waterfield N.K., Bowen D.J., Fetherston J.D., Perry R.D., ffrench-Constant R.H.; "The tc genes of Photorhabdus: a growing family."; Trends Microbiol. 9:185-191(2001).
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                                                                                                                                                                                                                                                                        Photochabdus luminescens (Xenorhabdus luminescens).
Bacteria; Proteobacteria; Gammaproteobacteria; Enterobacteriales;
Enterobacteriaceae; Photorhabdus.
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SEQUENCE 1476 AA; 165138 MW; 8E6AC3D109911995 CRC64;
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Last annotation update)
                                                                                IGREIKVITAKGWFRRTLFTPWFTVNEDENDTAAEV 1469
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Q93EP6;
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                                                        RSSSQFWLDDKAAALATGGTPVCYLPFPVHTLWQTETEDEISGNKLVTTLRYAHGAWDGR 780
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                                          YGFEIRTRRLCRQVLMYHHLQALDSKITEHNGPTLVSRLILNYDESAIASTLVFVRRVGH
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Qy 1374 IINVQHTENRWAVTGETEYDNKGQPIRTYQPYFLNI : :: :	1381	Qy 1434 IGREIKVITAKGMFRRTLFTPWFTVNEDENDTAAB 	SUL 893	AC 07N936; DT 01-MAR-2004 (TrEMBLrel. 26, Created) DT 01-MAR-2004 (TrEMBLrel. 26, Last sequence DT 01-MAR-2004 (TrEMBLrel. 26, Last annotation)			RX SIRAIN=110.10: RX BDLINE=110.10: RA Duchaud E., Rusnick C., Frangeul L., Buchries RA Taourit S., Bocs S., Boursaux-Eude C., Chand.	RA Dassa B., Derose R., Dereste S., Streyssiner RA A Zouine M., Glaser P., Boemare N., Danchin A. RT "The genome sequence of the entomopathogenic		DR GO; GO:0000.37; C:gytoghamm; IEA. DR GO; GO:0000150; C:integrin complex; IEA. DR GO; GO:0007160; P:cell-matrix adhesion; IEA. DR InterPro; IFR000413; Integrin alpha.		DR PRINTS; FYGUTA1; SALEYBERGI. DR PROSITE; PSG0626; RCC1_2; UNKNOWN_1. KW Complete proteome. SQ SEQUENCE 1485 AA; 166091 MW; 7BB5EB1AD50	Query Match 58.6%; Score 4627.5; Best Local Similarity 58.4%; Pred. No3.7e- Matches 869; Conservative 223; Mismatches	Qy 1 MQNSQDFSITELSLPKGGGAITGMGEALTPTGFDGB : :	Oy 61 SGAGNSPFGLGWDGNVMTIRRRTHFGVPHYDETDT 	0y	OY 172 QARISNESQTTQTAQWLLEASVSSRQEQIYYQYRAI	Qy 232 VYYGNRTASETLPGLDGSAPSQADMLFYLVFDYGEI	
295 YGFRIRTRRLCROVLMYHHLQALDSKITEHNGPTLVSRLILNYDESAIASTLVFVRRVGH 354		355 EQDGNVVILPPLELAYQDFSPRHHAHWQPMDVLANFNAIQRWQLVDLKGEGLDGLLYQDK 414 :	415 GAWWYRSAQRLGEIGSDAVTWEKMQPLSVIPSLQSNASLVDINGDGQLDWVITGPGLRGY 474	475 HSQRPDGSWTRFTPLNALPVEYTHPRAQLADLAGAGLSDLVLIGPKSVRLYANTRDGFAK 534	535 GKDVVQSGDITLPVPGADPRKLVAFSDVLGSGQAHLVEVSATKVTCWPNLGRGRFGQPIT 594	595 LPGFSQPATEFNPAQYYLADLDGSGPTDLIYVHTNRLDJFLNKSGNGFAEPVTLRPPEGL 654	655 RFDHTCQLQWADVQGLGVASLILSVPHWSPHHWRCDLTNWKPWLLNEWNNNMGVHHTLRY 714	715 RSSSQFWLDEKAAALTTGQTPVCYLPPPIHTLWQTETEDEISGNKLVTTLRYARGAWDGR 774 721 RSSVQFWLDEKAAALATGQTPVCYLPPPVHTLWQTETEDEISGNKLVTTLRYAHGAWDGR 780	775 BREFRGFGYVEQTDSHQLAQGNAPERTPPALTKNWYATGLPVIDNALSTEWR-DDQAFA 833 	834 GFSPRFTTWODNKDVPLTPEDDNSRYWFNRALKGOLIRSELYGLDDSTNKHVPYTVTEFR 893 : :	894 SQYRRLQHTDSRYPVLWSSVVBSRNYHYERIASDPQCSQNITLSSDRFGQPLKQLSVQYP 953 : : :	954 RRQQPAINLYPDTLPDKLLANSYDDQQRQLRLTYQQSSWHHLTNNTVRVLGLPDSTRSDI 1013 	1014 FTYGAENVPAGGIALELLSDKNSLIADDKPREYLGOOKTAYTDGONTTPLOTPTROALIA 1073 -	1074 FTETTVPNOSTLSAFNGSIPSDKLSTTLEQAGYQQTNYLPPRTGEDKVWVAHHGYTDYGT 1133	1134 AAQEWRPQKQSNTQLTGKITLIWDANYCVVVQTRDAAGLTTSAKYDWRFLTPVQLTDIND 1193 -	1194 NOHLITLDALGRPITLRFWGTRNGKWTGYSSPEKASFSPPSDVNAAIRLKKPLPVAQCQV 1253 	1254 YAPBSWMPVLSQKTFNRLAEQDWQKLYNARIITBDGRICTLAYRRWVQSQKAIPQLISLL 1313 : : :	1314 NNGPRLPPHSLTLTTDRYDHDPEQOIRQOVVFSDGFGRLLQAAARHEAGMARQRNEDGSL 1373 	
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